Appln. No.: 10/600,022

Appeal Brief Dated: March 23, 2009

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No:

10/600,022

Applicant:

Brent Gerberding et al.

Filed:

June 19, 2003

Title:

SANDWICHED RADIOPAQUE MARKERS ON COVERED STENT

T.C./A.U.:

3734

Examiner:

Suba Ganesan

Confirmation No.: 5691

Docket No.:

BSI-539US

APPEAL BRIEF IN SUPPORT OF NOTICE OF APPEAL

Mail Stop Appeal Brief - Patents

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Appellants hereby request reconsideration and reversal of the Rejection dated November 12, 2008 of claims 1-20 and 32-36.

This Brief is presented in the format required by 37 C.F.R. § 41.37, in order to facilitate review by the Board. In compliance with 37 C.F.R. § 41.37(a)(1), this Brief is being filed within the time allowed for response to the action from which the Appeal was taken or within one month from the mailing of the Notice of Panel Decision from Pre-Appeal Brief Review, whichever is later.

The fee (\$540) for filing a Brief in support of an Appeal under 37 C.F.R. § 41.20(b)(2) is provided herewith.

I. REAL PARTY IN INTEREST

The real party in interest is Boston Scientific Scimed, Inc., the assignee of record, which is a subsidiary of Boston Scientific Corporation.

II. RELATED APPEALS AND INTERFERENCES

There are no appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

Claims 1-36 are pending. Claims 1-20 and 32-36 stand rejected. Claims 21-31 have been withdrawn. Claims 1-20 and 32-36 are the subject of this appeal.

IV. STATUS OF AMENDMENTS

No amendments have been filed subsequent to the November 12, 2008 rejection.

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V. SUMMARY OF CLAIMED SUBJECT MATTER

As set forth in the pending independent apparatus claim 1, the presently claimed invention relates to a stent comprising a tubular expandable framework having an outer surface and an inner surface and a plurality of interconnected struts. The stent comprises a plurality of serpentine bands and further comprises a generally linear connector strut attaching a peak of one serpentine band to a trough of an adjacent serpentine band at the respective apices of each of the peak and the trough, wherein the respective apices are axially aligned with each other. The framework further comprises an outer covering of PTFE and an inner covering of PTFE, the outer covering extending along at least a portion of the outer surface of the expandable framework, the inner covering extending along at least a portion of the inner and outer coverings being contiguous. The stent further comprises at least one radiopaque marker disposed between the inner covering and the outer covering, the radiopaque marker being attached to the connector strut.

As explained in the specification, beginning on page 4, line 24, an exemplary embodiment of the presently claimed invention relates to a stent comprising a tubular expandable framework having an outer surface and an inner surface. The specification further explains on page 4, beginning on line 27, that the stent embodiment 100 includes a framework 104 comprising a plurality of interconnected struts 108, with the struts comprising a plurality of serpentine bands 106.

FIG. 3A of the specification (reproduced below), in conjunction with text in the specification beginning on page 6, line 9, for example, discloses a linear connector strut (identified as element 200 below) attaching a peak 132 of one serpentine band to a trough 136 of an adjacent serpentine band at the respective apices of each of the peak 132 and the trough 136, wherein the respective apices are axially aligned with each other.

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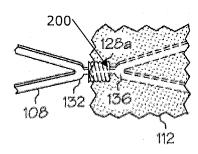


FIG. 3a

As further explained in the specification, beginning on page 5 at line 3, an exemplary embodiment of the framework further comprises an outer covering of PTFE and an inner covering of PTFE, the outer covering extending along at least a portion of the outer surface of the expandable framework, the inner covering extending along at least a portion of the inner surface of the expandable framework, and at least a portion of the inner and outer coverings being contiguous. Also, as explained in the specification, beginning on page 5 at line 24, an embodiment of the stent further comprises at least one radiopaque marker disposed between the inner covering and the outer covering. Further, as explained in the specification, beginning on page 6 at line 9, the radiopaque marker may be attached to the connector strut.

As set forth in the pending independent apparatus claim 20, the presently claimed invention relates to a stent comprising a tubular framework having an outer surface and an inner surface and a plurality of interconnected struts. The stent comprises a plurality of serpentine bands and further comprises a generally linear connector strut attaching a peak of one serpentine band to a trough of an adjacent serpentine band at the respective apices of each of the peak and the trough, wherein the respective apices are axially aligned with each other. The framework further comprises an outer covering of PTFE and an inner covering of PTFE, the outer cover extending along at least a portion of the outer surface of the framework, at least a portion of the inner and outer coverings being contiguous, the connector strut having at least one marker which is radiopaque or which may be visualized using magnetic resonance imaging. The marker is disposed between the inner covering and the outer covering.

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As explained in the specification, beginning on page 4 at line 24, an exemplary embodiment of the presently claimed invention relates to a stent comprising a tubular expandable framework having an outer surface and an inner surface and a plurality of interconnected struts. The specification further explains on page 4, beginning on line 27, that the stent embodiment 100 includes a framework 104 comprising a plurality of interconnected struts 108, with the struts comprising a plurality of serpentine bands 106.

FIG. 3A of the specification (reproduced above), in conjunction with text in the specification beginning on page 6 at line 9, for example, discloses a linear connector strut (identified as element 200 below) attaching a peak 132 of one serpentine band to a trough 136 of an adjacent serpentine band at the respective apices of each of the peak 132 and the trough 136, wherein the respective apices are axially aligned with each other.

As further explained in the specification, beginning on page 5 at line 3, an exemplary embodiment of the framework further comprises an outer covering of PTFE and an inner covering of PTFE, the outer covering extending along at least a portion of the outer surface of the expandable framework, the inner covering extending along at least a portion of the inner surface of the expandable framework, and at least a portion of the inner and outer coverings being contiguous. Also, as explained in the specification, beginning on page 5 at line 24 and illustrated in each of FIGS. 3a-3c, the strut embodiment has at least one marker which is radiopaque. Alternatively, as explained in the specification, beginning on page 7 at line 20, the marker may alternatively be visualized using magnetic resonance imaging. Further, as explained in the specification, beginning on page 5 at line 24, the marker is disposed between the inner covering and the outer covering.

As set forth in the pending independent apparatus claim 32, the presently claimed invention relates to a covered stent comprising a stent framework having an interior surface, an exterior surface and a marker region, the framework comprising a plurality of serpentine bands and further comprising a generally linear connector strut attaching a peak of one serpentine band to a trough of an adjacent

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serpentine band at the respective apices of each of the peak and the trough, wherein the respective apices are axially aligned with each other. At least one radiopaque marker is located within the marker region of said framework, the marker attached to the connector strut. A covering of expanded PTFE covers the interior surface and exterior surface of said framework in the marker region.

As explained in the specification, beginning on page 4 at line 24, an exemplary embodiment of the presently claimed invention relates to a stent comprising a stent framework having an interior surface, an exterior surface and a marker region. The illustrated framework embodiment comprises a plurality of serpentine bands. FIG. 3A of the specification (reproduced above), in conjunction with text in the specification beginning on page 6 at line 9, for example, discloses a linear connector strut (identified as element 200 above) attaching a peak 132 of one serpentine band to a trough 136 of an adjacent serpentine band at the respective apices of each of the peak 132 and the trough 136, wherein the respective apices are axially aligned with each other.

Also, as explained in the specification, beginning on page 5 at line 24 and illustrated in each of FIGS. 3a-3c, the strut embodiment has at least one marker which is radiopaque. FIG. 3A of the specification (reproduced above), in conjunction with text in the specification beginning on page 6 at line 9, for example, discloses a linear connector strut (identified as element 200 above) attaching a peak 132 of one serpentine band to a trough 136 of an adjacent serpentine band at the respective apices of each of the peak 132 and the trough 136, wherein the respective apices are axially aligned with each other.

As set forth in the pending independent apparatus claim 33, the presently claimed invention relates to a stent comprising a tubular expandable framework having an outer surface and an inner surface, the tubular expandable framework comprising a plurality of serpentine bands, adjacent serpentine bands having axially aligned oppositely pointing apices. The framework further includes linear connecting members connecting at least some of said oppositely pointing apices, an outer covering of PTFE and an inner covering of PTFE, the outer covering extending along at least a portion of the outer surface of the expandable framework, the inner

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covering extending along at least a portion of the inner surface of the expandable framework, at least a portion of the inner and outer coverings being contiguous. The stent further comprises at least one radiopaque marker disposed between the inner covering and the outer covering. The at least one radiopaque marker is attached to at least one of the linear connecting members.

As explained in the specification, beginning on page 4 at line 24, an exemplary embodiment of the presently claimed invention relates to a stent comprising a stent framework having an interior surface and an exterior surface. The framework comprises a plurality of adjacent serpentine bands having axially aligned oppositely pointing apices. FIG. 3A of the specification (reproduced above), in conjunction with text in the specification beginning on page 6 at line 9, for example, discloses a linear connector strut (identified as element 200 above) attaching a peak 132 of one serpentine band to a trough 136 of an adjacent serpentine band at the respective apices of each of the peak 132 and the trough 136.

As further explained in the specification, beginning on page 5 at line 3, the framework embodiment further comprises an outer covering of PTFE and an inner covering of PTFE, the outer covering extending along at least a portion of the outer surface of the expandable framework, with the inner covering extending along at least a portion of the inner surface of the expandable framework, and at least a portion of the inner and outer coverings being contiguous. Also, as explained in the specification, beginning on page 5 at line 24, the stent further comprises at least one radiopaque marker disposed between the inner covering and the outer covering. Further, as explained in the specification, beginning on page 6 at line 9, the radiopaque marker may be attached to the connector strut.

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VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Claims 1-4, 7, 9-20, and 32-36 as unpatentable under 35 U.S.C. §103(a) over U.S. Patent Application Publication No. 2004/0044399 to Ventura ("Ventura"), in view of U.S. Patent Application Publication No. 2002/0095205 to Edwin et al ("Edwin").

- B. Claims 5, 6 and 8 as unpatentable under 35 U.S.C. §103(a) over Ventura, in view of Edwin et al, and further in view of U.S. Patent Application Publication No. 2002/0193867 to Gladdish, Jr. et al ("Gladdish").
- C. Claims 14 and 15 as unpatentable under 35 U.S.C. §103(a) over Ventura, in view of Edwin et al, and further in view of U.S. Patent No. 6,488,701 to Nolting et al ("Nolting").

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VII. ARGUMENT

A. Claims 1-4, 7, 9-20, and 32-36 Are Patentable under 35 U.S.C. §103(a) over Ventura in View of Edwin

Claims 1-4, 7, 9-20, and 32 are being argued together. Claims 33-36 are being argued together.

1. Claims 1-4, 7, 9-20, and 32

Claims 1-4, 7, and 9-20, and 32 have been rejected under 35 U.S.C. §103(a) as unpatentable over Ventura in view of Edwin. It is respectfully submitted, however, that the pending claims are patentable over Ventura in view of Edwin in any reasonable combination for at least the reasons set forth below.

Independent claim 1 recites:

"A stent comprising a tubular expandable framework having an outer surface and an inner surface and a plurality of interconnected struts, the struts comprising a plurality of serpentine bands and further comprising a generally linear connector strut attaching a peak of one serpentine band to a trough of an adjacent serpentine band at the respective apices of each of the peak and the trough, wherein the respective apices are axially aligned with each other, the framework further comprising an outer covering of PTFE and an inner covering of PTFE, the outer covering extending along at least a portion of the outer surface of the expandable framework, the inner covering extending along at least a portion of the inner surface of the expandable framework, at least a portion of the inner and outer coverings being contiguous, the stent further comprising at least one radiopaque marker disposed between the inner covering and the outer covering, the radiopaque marker attached to the connector strut."

Independent claim 20 recites:

"A stent comprising a tubular framework having an outer surface and an inner surface and a plurality of interconnected struts, the struts

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comprising a plurality of serpentine bands and further comprising a generally linear connector strut attaching a peak of one serpentine band to a trough of an adjacent serpentine band at the respective apices of each of the peak and the trough, wherein the respective apices are axially aligned with each other, the framework further comprising an outer covering of PTFE and an inner covering of PTFE, the outer cover extending along at least a portion of the outer surface of the framework, at least a portion of the inner and outer coverings being contiguous, the connector strut having at least one marker which is radiopaque or which may be visualized using magnetic resonance imaging, the marker disposed between the inner covering and the outer covering."

Independent claim 32 recites:

"A covered stent comprising:

a stent framework having an interior surface, an exterior surface and a marker region, the framework comprising a plurality of serpentine bands and further comprising a generally linear connector strut attaching a peak of one serpentine band to a trough of an adjacent serpentine band at the respective apices of each of the peak and the trough, wherein the respective apices are axially aligned with each other;

at least one radiopaque marker located within the marker region of said framework, the marker attached to the connector strut; and a covering of expanded PTFE covering the interior surface and exterior surface of said framework in the marker region."

Each of independent claims 1, 20, and 32 recites the feature of a stent comprising a framework having a plurality of serpentine bands and further comprising a generally linear connector strut attaching a peak of one serpentine band to a trough of an adjacent serpentine band at the respective apices of each of the peak and the trough, wherein the respective apices are axially aligned with each other.

"The Patent and Trademark Office ("PTO") determines the scope of claims in patent applications not solely on the basis of the claim language, but upon giving

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claims their broadest reasonable construction 'in light of the specification as it would be interpreted by one of ordinary skill in the art." *Phillips v. AWH Corp.*, 75 U.S.P.Q.2d 1321, 1329 (CAFC 2005).

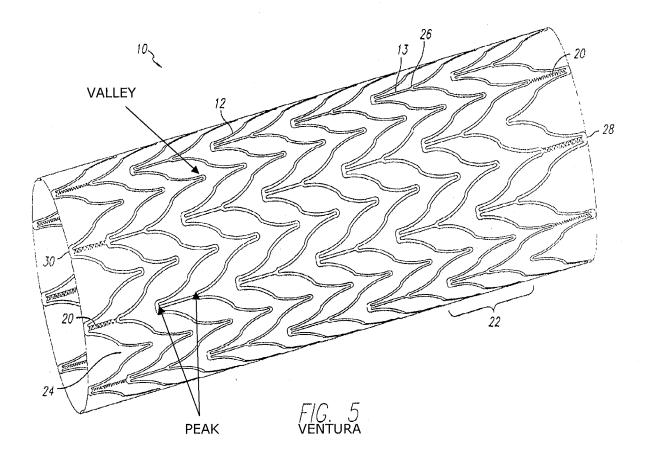
The specification, starting on page 6 at line 9, and taken in conjunction with FIG. 3a, clearly discloses an embodiment having a peak (132) on one serpentine band that points toward the right in Fig. 3a and a trough (136) on an adjacent serpentine band that points to left (opposite the direction of the peak 132). The apices of peaks 132, 136 are axially aligned with one another (along the length of the connecting strut). Contrary, then, to the Office Action's position taken in the November 12, 2008 Office Action, on page 2, paragraph 1, that the "selection of a peak vs. a trough is arbitrary," Applicants respectfully submit that the specification discloses a peak that points in one direction and a trough that points in the opposite direction from the peak.

Therefore, by giving the claims their broadest reasonable interpretation *in* light of the specification, the claimed peak clearly extends toward one direction (e.g., to the right) and the claimed trough clearly extends toward an opposite direction (e.g., to the left).

In contrast, Ventura discloses a stent having a plurality of adjacent cylindrical elements, with each adjacent cylindrical element being connected by interconnecting elements in a *peak-to-peak* (or, conversely, valley-to-valley) design due to the alignment of adjacent cylindrical elements along the longitudinal stent axis. *See* Ventura, annotated Fig. 5, below.

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By disclosing each adjacent cylindrical element being connected *peak-to-peak* (or, conversely, valley-to-valley) due to the alignment of the adjacent cylindrical elements along the longitudinal stent axis, Ventura fails to disclose a stent having the claimed feature of a generally linear connector strut attaching *a peak of one serpentine band to a trough of an adjacent serpentine band* at the respective apices of each of the peak and the trough, wherein the respective apices are axially aligned with each other, as recited in each of claims 1, 20, and 32.

Edwin is cited for allegedly using an inner and outer covering of expanded polytetrafluoroethylene (ePTFE). Edwin fails to disclose or suggest the claimed feature of a generally linear connector strut attaching a peak of one serpentine band to a trough of an adjacent serpentine band, as recited in each of claims 1, 20, and 32. Applicants respectfully submit that Edwin fails to cure the deficiencies of Ventura regarding claims 1, 20, and 32 of the present invention, and thus the proposed combination of Ventura with Edwin fails to establish a prima facie case of obviousness.

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Applicants therefore respectfully submit that the rejection of independent claims 1, 20, and 32 is improper, and respectfully request reconsideration and allowance of the claims. Claims 2-4, 7, and 9-19 all ultimately depend from claim 1. It is respectfully submitted that the cited references, alone or in any reasonable combination, fail to teach or suggest each limitation of the claimed invention for at least the reasons set forth above with respect to claim 1. Appellants respectfully request reconsideration and reversal of the rejection of claims 1-4, 7, 9-20, and 32 under 35 U.S.C. §103(a).

2. Claims 33-36

Claims 33-36 have been rejected under 35 U.S.C. §103(a) as unpatentable over Ventura in view of Edwin. It is respectfully submitted, however, that the pending claims are patentable over Ventura in view of Edwin in any reasonable combination for at least the reasons set forth below.

Independent claim 33 recites:

"A stent comprising a tubular expandable framework having an outer surface and an inner surface, the tubular expandable framework comprising a plurality of serpentine bands, adjacent serpentine bands having axially aligned oppositely pointing apices, said framework further including linear connecting members connecting at least some of said oppositely pointing apices, an outer covering of PTFE and an inner covering of PTFE, the outer covering extending along at least a portion of the outer surface of the expandable framework, the inner covering extending along at least a portion of the inner surface of the expandable framework, at least a portion of the inner and outer coverings being contiguous, the stent further comprising at least one radiopaque marker disposed between the inner covering and the outer covering, the at least one radiopaque marker attached to at least one of the linear connecting members."

The November 12, 2008 Office Action alleges on page 2, paragraph 2, that the claimed limitation of "adjacent serpentine bands having axially aligned oppositely pointing apices" does not exclude the interpretation as adjacent

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serpentine bands, <u>the bands</u> being axially aligned and having oppositely pointing apices. Applicants respectfully traverse this improper conclusion.

As discussed above, a claim must be given its broadest reasonable interpretation *in light of the specification*. The specification does not support the Office Action's erroneous interpretation of "adjacent serpentine bands, <u>the bands</u> being axially aligned and having oppositely pointing apices." To the contrary, the specification supports the interpretation of adjacent serpentine bands that have axially aligned apices that are oppositely pointing, as is illustrated in exemplary embodiments of the claimed invention in each of FIGS. 3a-3c of the application. FIG. 3a is reproduced above. FIGS. 3b and 3c are reproduced below, with FIG. 3b being annotated to illustrate exemplary claimed features.

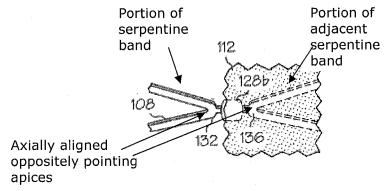


FIG. 3b

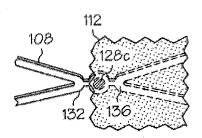


FIG. 3c

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Further, the Office Action's interpretation of "the bands being axially aligned" does not make any sense, particularly in light of the specification. The Office Action's interpretation of the bands being axially aligned allows for multiple interpretations, such as, for example, as central axis of adjacent bands being axially aligned with each other, or, alternatively, a surface of adjacent bands being axially aligned with each other, with the central axes of those bands not being axially aligned with each other.

The interpretation that is supported by the specification is the only reasonable interpretation for the claim language, that being that adjacent serpentine bands have axially aligned apices that are oppositely pointing.

Edwin is cited for allegedly using an inner and outer covering of expanded polytetrafluoroethylene (ePTFE). Edwin fails to disclose or suggest the claimed feature of adjacent serpentine bands having axially aligned oppositely pointing apices, as recited in claim 33. Applicants respectfully submit that Edwin fails to cure the deficiencies of Ventura regarding claim 33 of the present invention, and thus the proposed combination of Ventura with Edwin fails to establish a prima facie case of obviousness.

It is respectfully submitted that the cited references, alone or in any reasonable combination, fail to teach or suggest each limitation of the claimed invention. Claims 34-36 all ultimately depend from claim 33. It is respectfully submitted that the cited references, alone or in any reasonable combination, fail to teach or suggest each limitation of the claimed invention for at least the reasons discussed above in connection with claim 33. Appellants respectfully request reconsideration and reversal of the rejection of claims 33-36 under 35 U.S.C. §103(a).

B. Claims 5, 6, and 8 Are Patentable over Ventura, in View of Edwin et al., and Further in View of Gladdish

Claims 5, 6, and 8 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Ventura, in view of Edwin et al, and further in view of Gladdish. Claims 5, 6, and 8 ultimately depend from claim 1. Gladdish is cited for allegedly applying the marker to the stent via crimping, embedding, or inserting a plug into an opening in

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the stent framework. Applicants respectfully submit that Gladdish fails to cure the deficiencies of Ventura or Edwin regarding claim 1 of the present invention. Applicants respectfully submit that these claims are allowable over the cited prior art for at least the same reasons as set forth above with respect to claim 1. Reconsideration and allowance of the claims are respectfully requested.

It is respectfully submitted that the cited references, alone or in any reasonable combination, fail to teach or suggest each limitation of the claimed invention. Appellants respectfully request reconsideration and reversal of the rejection of claims 5, 6, and 8 under 35 U.S.C. §103(a).

C. Claims 14 and 15 Are Patentable over Ventura, in View of Edwin et al., and Further in View of Nolting

Claims 14 and 15 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Ventura, in view of Edwin et al, and further in view of Nolting. Claims 14 and 15 ultimately depend from claim 1. Nolting is cited for the use of stents for correcting cerebral vasculature. Applicants respectfully submit that Nolting fails to cure the deficiencies of Ventura or Edwin regarding claim 1 of the present invention. Applicants respectfully submit that these claims are allowable over the cited prior art for at least the same reasons as set forth above with respect to claim 1. Reconsideration and allowance of the claims are respectfully requested.

It is respectfully submitted that the cited references, alone or in any reasonable combination, fail to teach or suggest each limitation of the claimed invention. Appellants respectfully request reconsideration and reversal of the rejection of claims 14 and 15 under 35 U.S.C. §103(a).

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VIII. CONCLUSION

In view of the arguments set forth above, all pending claims are patentable over the cited references. The rejection of all of the pending claims of record should therefore be reversed with instructions to issue a Notice of Allowability. Such actions are respectfully requested.

Respectfully Submitted,

RatnerPrestia

Joshka L. Cohen, Reg. No. 38,040 Joseph E. Maenner, Reg. No. 41,964

Attorneys for Appellants

JLC/JEM/ch

Enclosures:

Claims Appendix

Evidence Appendix

Related Proceedings Appendix

Dated:

March 23, 2009

P.O. Box 980

Valley Forge, PA 19482-0980

(610) 407-0700

The Commissioner for Patents is hereby authorized to charge payment to Deposit Account No. 18-0350 of any fees associated with this communication.

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CLAIMS APPENDIX

1. A stent comprising a tubular expandable framework having an outer surface and an inner surface and a plurality of interconnected struts, the struts comprising a plurality of serpentine bands and further comprising a generally linear connector strut attaching a peak of one serpentine band to a trough of an adjacent serpentine band at the respective apices of each of the peak and the trough, wherein the respective apices are axially aligned with each other, the framework further comprising an outer covering of PTFE and an inner covering of PTFE, the outer covering extending along at least a portion of the outer surface of the expandable framework, the inner covering extending along at least a portion of the inner surface of the expandable framework, at least a portion of the inner and outer coverings being contiguous, the stent further comprising at least one radiopaque marker disposed between the inner covering and the outer covering, the radiopaque marker attached to the connector strut.

- 2. The stent of claim 1 wherein the PTFE is in the form of expanded PTFE.
- 3. The stent of claim 1 wherein the radiopaque marker is in the form of a radiopaque marker band.
- 4. The stent of claim 3 wherein the marker band is wound about a portion of the stent.
- 5. The stent of claim 3 wherein the marker band is crimped to the stent framework
- 6. The stent of claim 1 wherein the radiopaque marker is embedded in a portion of the stent framework.
- 7. The stent of claim 1 wherein the radiopaque marker is located adjacent an uncovered region of the stent.

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8. The stent of claim 1 wherein the radiopaque marker is in the form of a radiopaque plug which is inserted into an opening in the stent framework.

- 9. The stent of claim 1 comprising a plurality of radiopaque markers.
- 10. The stent of claim 9 wherein the PTFE is in the form of expanded PTFE.
- 11. The stent of claim 10 wherein the PTFE on the outer surface and the PTFE on the inner surface of the framework are coextensive with one another.
- 12. The stent of claim 11 wherein at least some of the radiopaque markers indicate at least one end of the PTFE on the inner and outer surfaces.
- 13. The stent of claim 11 wherein at least some of the radiopaque markers indicate a first end of the PTFE on the inner and outer surfaces and others of the radiopaque markers indicate a second end of the PTFE on the inner and outer surfaces.
- 14. The stent of claim 13 sized for use in a cranial vessel.
- 15. The stent of claim 1 sized for use in a cranial vessel.
- 16. The stent of claim 1 wherein the radiopaque marker does not protrude beyond the outer surface and inner surfaces of the stent framework.
- 17. The stent of claim 11 wherein the radiopaque markers do not protrude beyond the outer surface and inner surfaces of the stent framework.
- 18. The stent of claim 12 wherein the radiopaque markers do not protrude beyond the outer surface and inner surfaces of the stent framework.
- 19. The stent of claim 13 wherein the radiopaque markers do not protrude beyond the outer surface and inner surfaces of the stent framework.

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20. A stent comprising a tubular framework having an outer surface and an inner surface and a plurality of interconnected struts, the struts comprising a plurality of serpentine bands and further comprising a generally linear connector strut attaching a peak of one serpentine band to a trough of an adjacent serpentine band at the respective apices of each of the peak and the trough, wherein the respective apices are axially aligned with each other, the framework further comprising an outer covering of PTFE and an inner covering of PTFE, the outer cover extending along at least a portion of the outer surface of the framework, at least a portion of the inner and outer coverings being contiguous, the connector strut having at least one marker which is radiopaque or which may be visualized using magnetic resonance imaging, the marker disposed between the inner covering and the outer covering.

- 21. (Withdrawn) A method of manufacturing a stent comprising the steps of providing a stent framework comprising a plurality of interconnected struts, the framework having an inner surface and an outer surface; providing radiopacity to the stent framework in a desired region of the framework covering the inner surface of the stent framework in the desired region of the stent framework with PTFE; covering the outer surface of the stent framework in the desired region of the stent framework with PTFE.
- 22. (Withdrawn) The method of claim 21 further comprising the steps of: providing radiopacity to the stent framework in a plurality of desired regions; covering the outer and inner surfaces of the stent framework with PTFE in each of the desired regions.
- 23. (Withdrawn) The method of claim 22 wherein the radiopacity is provided via radiopaque markers which are attached to the stent framework.
- 24. (Withdrawn) The method of claim 23 wherein each radiopaque marker is in the form of a radiopaque material which is wound around a portion of the stent framework.

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25. (Withdrawn) The method of claim 23 wherein each radiopaque marker is in the form of a radiopaque plug which is inserted into an opening in the stent framework.

- 26. (Withdrawn) The method of claim 21 wherein the radiopacity is provided in the form of a marker which marks an end of the PTFE on the inner and outer surface of the stent.
- 27. (Withdrawn) The method of claim 22 wherein the radiopacity is provided in the form of a plurality of markers which mark at least one end of the PTFE on the inner and outer surface of the stent.
- 28. (Withdrawn) The method of claim 27 wherein the PTFE on the inner and outer surfaces of the stent are coextensive with one another.
- 29. (Withdrawn) The method of claim 21 wherein the PTFE on the inner and outer surfaces of the stent are coextensive with one another.
- 30. (Withdrawn) The method of claim 28 wherein the PTFE on the inner surface is in the form of a first extruded tube of expanded PTFE and the PTFE on the outer surface is in the form of a second extruded tube of expanded PTFE.
- 31. (Withdrawn) The method of claim 21 wherein the stent is sized for use in a cranial vessel.

32. A covered stent comprising:

a stent framework having an interior surface, an exterior surface and a marker region, the framework comprising a plurality of serpentine bands and further comprising a generally linear connector strut attaching a peak of one serpentine band to a trough of an adjacent serpentine band at the respective apices of each of the peak and the trough, wherein the respective apices are axially aligned with each other;

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at least one radiopaque marker located within the marker region of said framework, the marker attached to the connector strut; and a covering of expanded PTFE covering the interior surface and exterior surface of said framework in the marker region.

- 33. A stent comprising a tubular expandable framework having an outer surface and an inner surface, the tubular expandable framework comprising a plurality of serpentine bands, adjacent serpentine bands having axially aligned oppositely pointing apices, said framework further including linear connecting members connecting at least some of said oppositely pointing apices, an outer covering of PTFE and an inner covering of PTFE, the outer covering extending along at least a portion of the outer surface of the expandable framework, the inner covering extending along at least a portion of the inner surface of the expandable framework, at least a portion of the inner and outer coverings being contiguous, the stent further comprising at least one radiopaque marker disposed between the inner covering and the outer covering, the at least one radiopaque marker attached to at least one of the linear connecting members.
- 34. The stent of claim 33, wherein both the inner covering and the outer covering do not extend along at least a portion of the expandable framework.
- 35. The stent of claim 33, wherein the expandable framework extends beyond both the inner covering and the outer covering.
- 36. The stent of claim 33, wherein at least a portion of the inner covering is laminated to at least a portion of the outer covering.
- 37-39. (Canceled).

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EVIDENCE APPENDIX

None

RELATED PROCEEDINGS APPENDIX

None